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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,684	07/17/2003	Scott A. Waldman	TJU-2858	1770

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EXAMINER	
PONNALURI, PADMASHRI	
ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 02/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/621,684	WALDMAN, SCOTT A.	
	Examiner	Art Unit	
	Padmashri Ponnaluri	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-28,30-34,36 and 38-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-28, 30-34, 36, 38-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment and response filed on 11/2/05 has been fully considered and entered into the application.

2. New claims 45-47 have been added, and claims 29, 35 and 37 have been canceled by the amendment filed on 11/2/05.

3. Claims 23-28, 30-34, 36, 38-47 are currently pending and are being examined in this application.

Priority

4. This application is a continuation of 09/263,477, which is a continuation of 08/583,447, which is a continuation-in-part of 08/141,892.

5. Claims 25, 32, and 43 recite SEQ ID NO: 55 and 56 as the ST receptor binding ligand peptides, which were not disclosed in the parent applications, 08/141,892, filed on 10/26/93. In a continuation-in-part application, only claims directed solely subject matter adequately disclosed under 35 USC 112, first paragraph in the parent application is entitled to the benefit of the filing date of the parent application. Thus, the instant claims 25, 32, 43, which recite sequences not disclosed in the parent applications are entitled only to the filing date of the continuation-in-part application. See MPEP 201.22.

Withdrawn Claim Rejections

6. The Scope enablement rejection of claims 23-25, 28-32, 35-37, 39, 41-43 under 35 U.S.C. 112, first paragraph, set forth in the previous office action has been withdrawn.

7. The rejection of claims 23-44 under 35 U.S.C. 112, Second paragraph has been withdrawn in view of the amendment to the claims.

8. The written description rejection over claims 24-27, 32-34, 36, 38-40, 43-45 has been withdrawn in view of applicant's arguments (See the response to the arguments).

9. The rejection of claims 23-27 and 41 under 35 U.S.C. 102(b) as being anticipated by US Patent 4,490,080 (Duflot et al) set forth in the previous office action has been withdrawn in view of the amendment to the claims.

10. The rejection of claims 23-24 and 41 under 35 U.S.C. 102(b) as being anticipated by US Patent 4,411,888 (Klipstein et al) set forth in the previous office action has been withdrawn in view of the amendment to the claims.

11. The obviousness-type-double Patenting rejection of claims 23-44 over claims 1-22 of U.S. Patent No. 5,518,888, set forth in the previous office action has been withdrawn in view of applicants arguments, that the reference claim method was restricted from the product claims of the instant application.

12. The obviousness-type-double Patenting rejection of claims 23-44 over claims 1-58 of U.S. Patent No. 5,879,656, set forth in the previous office action has been withdrawn in view of applicants arguments, that the reference claim method was restricted from the product claims of the instant application.

Maintained Claim Rejections

13. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

14. The written description rejection of claims 23, 28, 30-31, 41-42 under 35 U.S.C. 112, first paragraph, set forth in the previous office action has been maintained for the reasons of record.

15. The rejection of claims 23-28, 41-42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,962,220, set forth in the previous office action has been maintained for the reasons of record.

16. The rejection of claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,060,037, set forth in the previous office action has been maintained for the reasons of record.

17. The rejection of claims 23-28 and 41-42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,087,109, set forth in the previous office action has been maintained for the reasons of record.

18. The provisional rejection of claims 23-25, 28-32, 35-36, 41-42 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 10, 32, 37, 9, 41-42, 54-55, 58, 63-64, 92, 96-97, 99, 102, 108, 109, 114, 116, 118-119, 125-153 of copending Application No. 08/468,449, set forth in the previous office action has been maintained for the reasons of record.

Response to Arguments

19. Claims 23-25, 28-32, 35-37, 39, and 41-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is Written Description Rejection.

The instant claims recite a pharmaceutical composition comprising: a ST receptor binding ligand and a radio-stable active agent.

The specification discloses St receptor binding ligand is a ST receptor binding peptide of sequence SEQ ID NO: 2, 3, and 5-56 and fragments and derivatives. The specification discloses ST receptor binding peptides with amino acid sequence of SEQ ID NO: 2, 3 and 5 and fragments and derivatives of the sequences of SEQ ID NO: 2, 3 and 5 (SEQ ID NO: 6-56). The specification has not disclosed fragments or derivatives of peptide sequences of SEQ ID NO: 6-56. The specification does not teach any other compounds as the ST receptor binding ligands. However, claims 23-25, 28-32, 35-37, 39, 41-43 directed to encompass fragments and derivatives to SEQ ID No: 6-56, and sequences from other species, mutated sequences, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: XXX, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

> ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood* , 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel* , 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Id. at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only SEQ ID NO: 2, 3, 5-56 but not the full breadth of the claim meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded

that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision.

20. Applicant's arguments filed on 11/2/05 have been fully considered but they are not persuasive.

Applicant's arguments regarding 'ST receptor binding ligand' as a peptide is fully considered. The written description rejection over claims 24-27, 32-34, 36, 38-40, 43-45 has been withdrawn. However, the rejection of record would still be applicable to claims 23, 28, 30-31, 41-42. In claims 23, 28, 30-31, 41-42, the 'ST receptor binding ligand' is not limited to peptides. The ST receptor binding ligand can be a non-peptide. The specification has not disclosed any non-peptide compounds as ST receptor binding ligands. The specification has no examples of non-peptide compounds as ST receptor binding ligands.

The specification in page 17 discloses that 'it is preferred that the ST receptor binding ligand used as the ST receptor binding moiety be as small as possible. Thus, it is preferred that the ST receptor binding ligand be a non-peptide small molecule or small peptide, preferably less than 25 amino acids...' Thus, the specification discloses that small peptides as ST receptor binding ligands. However, the specification has not disclosed any of the non-peptide small molecules as ST receptor binding ligands. The example 1 in the specification discloses the compounds, none of which have a non-peptide compound as ST receptor binding ligands. And the rest of examples disclose that the ST receptor binding ligands have 'free amino group such as the ST receptor binding peptides.' And the specification discloses methods of identifying ST receptor binding ligands such as peptides from the combinatorial libraries, but not of any non-

peptide compounds. Thus, the specification has not sufficiently described the possession of the compounds other than the peptides as 'ST receptor biding ligands. Thus, the instant specification disclosure clearly not representative of the scope of the presently claimed ST receptor binding ligands. The rejection of record has been maintained.

21. Claims 23-28, 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. 5,962,220. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference patent claim discloses pharmaceutical compositions comprising peptides as ST receptor binding moiety, and antisense molecule as active moiety, which would read on the therapeutic agent of the instant claims, and the modes of administration of the reference is within the scope of the presently claimed invention.

22. Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,060,037. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference patent claim discloses pharmaceutical compositions comprising peptides as ST receptor binding moiety, and the reference active moiety is a therapeutic agent, which would read on the therapeutic agent of the instant claims, and the modes of administration of the reference is within the scope of the presently claimed invention.

23. Claims 23-28 and 41-42 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,087,109. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference patent claim discloses pharmaceutical compositions comprising peptides as

ST receptor binding moiety, and antisense molecule as active moiety, which would read on the therapeutic agent of the instant claims, and the modes of administration of the reference is within the scope of the presently claimed invention.

24. Claims 23-25, 28-32, 35-36, 41-42 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 8, 10, 32, 37, 9, 41-42, 54-55, 58, 63-64, 92, 96-97, 99, 102, 108, 109, 114, 116, 118-119, 125-153 of copending Application No. 08/468,449. Although the conflicting claims are not identical, they are not patentably distinct from each other because the reference pharmaceutical composition (i.e., claims 10, 32, 63) comprises a conjugated compound comprising an ST receptor binding moiety, and an active moiety, which read on the instant claim. The reference claim 32 does not specify that the ST receptor binding moiety is an antibody, thus it reads on the instant claim peptides as ST receptor binding moiety of the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

25. *Applicant's arguments filed on 11/2/05 regarding the ODP rejections of record over US Patents 6,087,109; 5,962,220; 6,060,037; and provisional rejection over US Patent application 08/468,449, have been fully considered but they are not persuasive.*

Regarding the ODP rejection over US Patents 6,087,109; 5,962,220; and provisional rejection over US Patent application 08/468,449, applicants state that 'applicants would file such a terminal disclaimer upon indication that claims would be otherwise allowable.'

However, applicants have not filed the TDs to overcome the ODP rejections over these references, the rejections of record have been maintained.

Applicants traverse the ODP rejection over US Patent 6,060,037. Applicants argue that the `037 patent claims are directed to methods of imaging colorectal tumors, in vitro methods of screening individuals, methods of treating colorectal tumors, methods of delivering nucleic acid molecules and kits. And the invention claimed in `037 patent corresponds to the non-elected groups in the present application, and the patent has no claims to conjugated compounds.

Applicants arguments and assertions regarding the `037 patent claims have been considered and are not persuasive. Because the original claims in the instant application 10/621,684 are drawn to pharmaceutical compositions, and methods of use of the compositions in in-vivo methods. The independent claims in `037 patent are drawn to 'method of radio imaging metastasized colorectal cancer cells by administering to an individual' (in vivo radio imaging, claim 1); and claim 3 is drawn to 'in vitro method of screening an individual'; claim 5 is drawn to 'in vitro method of determining whether tumor cell is a colorectal tumor cell'; and claim 10 recites a 'kit for determining whether a sample contains a colorectal caner cell.' And all the `037 patent method claims use the composition of the instant claims. In the instant application (10/621,684) only the methods of use of the compositions comprising 'ST receptor binding ligands' in in-vivo methods were restricted from the compositions comprising 'ST receptor binding ligands.' The instant application does not have 'methods of use of ST receptor binding ligands in vitro. Thus, the obviousness-type double patenting rejection over the `037 patent is proper.

Conclusion

26. No claims are allowed.

27. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padmashri Ponnaluri whose telephone number is 571-272-0809. The examiner can normally be reached on Monday through Friday between 7 AM and 3.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Padmashri Ponnaluri
Primary Examiner
Art Unit 1639

PADMASHRI PONNALURI
PRIMARY EXAMINER

26 January 2006